

Risedronate treatment for Children with severe Osteogenesis Imperfecta

Submission date 04/02/2002	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 04/02/2002	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 03/11/2011	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
B0696

Study information

Scientific Title

Bisphosphonate administration in children with severe osteogenesis imperfecta: A prospective randomised double blind controlled study of risedronate

Acronym

RICO trial

Study objectives

Children aged between four and seventeen who have osteogenesis imperfecta, which is a form of osteoporosis which causes multiple fractures, deformity and stunted growth, are to be offered Risedronate in a clinical trial aimed at increasing bone density.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Sheffield Research Ethics Committee. Date of approval: 06/12/1999 (ref: SS 98/183)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteogenesis imperfecta

Interventions

Patients will be randomised to either low (0.2 mg/kg/week), medium (1 mg/kg/week) or high (2 mg/kg/week) dose of the bisphosphonate risedronate. Treatment will continue for 3 years.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bisphosphonate risedronate

Primary outcome(s)

Added as of 10/04/2008:

Number of incident non-vertebral fractures in each group at 2 years.

Key secondary outcome(s)

Added as of 10/04/2008:

The following were assessed at 2 years:

1. Total body and lumbar spine bone area
2. Bone mineral content
3. Areal bone mineral density and volumetric bone mineral density

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Inclusion criteria amended as of 15/04/2008:

1. Children with osteogenesis imperfecta
2. Aged between 3 and 17 ("Aged between 4 and 17" at ethics approval. We subsequently had an approved amendment to reduce the lower age limit to 3 years; this applied to only one child)
3. Both male and female

Inclusion criterion provided at time of registration:

Children with osteogenesis imperfecta

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Years

Upper age limit

17 Years

Sex

All

Key exclusion criteria

Added as of 10/04/2008:

1. Have a history of cancer
2. Have untreated rickets within one year prior to enrollment
3. Evidence of clinically significant organic or psychiatric disease on history or physical examination which in the opinion of the investigator would prevent the patient from completing the study
4. Have markedly abnormal pretreatment laboratory findings, except if in the opinion of the investigator, it would not prevent the patient from completing the study
5. Have a history of using anabolic steroids/estrogens/androgens within one year of enrollment
6. Have a history of using any of the following medications within 6 month of starting study drug for more than one month: calcitonin, vitamin D supplements >1000 IU per day, and calcitriol >1.5 mg/week

7. Have a history of using any bisphosphonate (except for more than a single dose of risedronate) and/or fluoride (>10 mg per day). Have a documented history of an abnormal or allergic reaction to bisphosphonates
8. Pregnancy or sexually active subjects unwilling to take appropriate contraceptive measures
9. Any limb-lengthening procedure within 6 of enrollment
10. Participation in another clinical trial, involving active intervention within 30 days prior to enrollment
11. Serum creatinine >150 µmol/L

Date of first enrolment

31/07/2001

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Institute of Child Health

Sheffield

United Kingdom

S10 2TH

Sponsor information

Organisation

Arthritis Research Campaign (ARC) (UK)

ROR

<https://ror.org/02jkpm469>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (ARC) (UK)

Funder Name

Alliance for Better Bone Health (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No